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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/760,520

01/21/2004

David I. Freed

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22852

7590

09/05/2007

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER
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EXAMINER

KASZTEJNA, MATTHEW JOHN

ART UNIT

PAPER NUMBER

3739

MAIL DATE

DELIVERY MODE

09/05/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/760,520

Applicant(s)

FREED, DAVID I.

Examiner

Matthew J. Kasztejna

Art Unit

3739

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 June 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 10-21, 23-37, 39-53, 56-64 and 66-102 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Continuation of Disposition of Claims: Claims pending in the application are 1-7,10-18,28-37,39,40,43-53,56,58-64,66,67,69-75,81,82,87-89,93 and 97-102.

Continuation of Disposition of Claims: Claims withdrawn from consideration are 19-21,23-27,41,42,57,68,76-80,83-86,90-92 and 94-96.

DETAILED ACTION

Notice of Amendment

In response to the amendment filed on June 22, 2007 amended claims 1, 30, 34, 47, 59 and 97-100; canceled claims 8, 38, 54 and 65; and new claims 101-102 are acknowledged. The following new and reiterated grounds of rejection are set forth:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4, 10-18, 28-30, 31-37, 39-40, 43-44, 45-46, 47-52, 53, 56, 58-64, 66-67 and 97-100 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,682,599 to Konomura in view of U.S. Patent No. 6,660,011 to Levinson.

In regards to claims 1, 28, 34, 47-52, 58-63 and 97-100, Konomura discloses a medical device comprising: a proximal handle; an elongated member 2 having a proximal end, a distal end, and a lumen there between, the proximal end being coupled to the proximal handle, the elongated member being sufficiently flexible to traverse through tortuous anatomy of a patient's body; an end effector 6 proximate the distal end of the elongated member, actuation of the proximal handle 14 causing the end effector to perform a medical procedure; and a distal member configured to open and substantially close the distal end of the lumen, the distal member defining a flow path such that, when the distal member substantially closes the distal end of the lumen, the

Art Unit: 3739

flow path enables a flow communication between the lumen and an outside of the elongated member (see Figs. 1 and 2, and Col. 4, Lines 1-14). Konomura is silent with respect to a tissue cutting end effector wherein actuation of the proximal handle causes the end effector to sever tissue. Konomura teaches of wires 6 used for holding or fracturing a foreign matter. Levinson teaches of an analogous medical device used for tissue cutting and retrieval, having a tissue cutting end effector that is a snare loop 28 (see Fig. 5). The device consists of a set of wires 28 used for selectively cutting tissue within the body, as the wires 28 may be energized so that the wires cut tissue captured within the wires 28 (see Figs. 1 and 9). It would have been obvious to one skilled in the art at the time the invention was made to have a tissue cutting end effector in the apparatus of Konomura to selectively capture, cut and/or retrieve polyps and other aggregates of organic tissue from a patient's internal organs as taught by Levinson.

In regards to claims 2, 35 and 66, Konomura discloses a medical device wherein the flow path defined by the distal member has a cross-sectional flow area less than a cross-sectional flow area of the lumen (see Fig. 2)

In regards to claims 3-4 and 36, Konomura discloses a medical device including a port 10 which is in fluid communication with the lumen and comprises a fluid supplying member for supplying fluid to the port (see Col 3, Lines 20-25).

In regards to claims 10-13 and 37, Konomura discloses a medical device wherein the distal member includes a sealing member 7. At least a portion of the distal member has a frusto-conical shape for substantially closing the lumen. The distal member includes a base portion and a head portion, the base portion having an outer

Art Unit: 3739

diameter substantially the same as an inner diameter of the lumen, the head portion having an outer diameter greater than the inner diameter of the lumen. Also, the distal member includes a plate member having an outer diameter substantially the same as the inner diameter of the lumen (see Col. 3, Line 64 – Col. 4, Line 13).

In regards to claims 14-15, Konomura discloses a medical device wherein at least a portion of the flow path has a cross-sectional flow area smaller than that of at least one of an inlet and an outlet of the flow path (see Col. 4, Lines 36-68).

In regards to claims 16-18, 39-40, 43-44, 56 and 67, Konomura discloses a medical device wherein the distal member connects to the end effector at a distal end of the end effector and the distal member is movable relative to the lumen and is configured to substantially close the lumen when the end effector retracts (see Fig. 1 and Col. 4, Lines 1-14).

In regards to claims 28-30, Konomura discloses a medical device wherein the handle includes a stationary part 15 and movable part 14. Further comprising a control member 5 having a proximal end coupled to the movable part and a distal end coupled to the end effector so that actuation of the movable part relative to the stationary part enables movement of the end effector for performing the medical procedure (see Fig. 1 and Col. 3, Lines 26-47).

In regards to claims 31-32, 45, 53 and 64 Konomura discloses a medical device but is silent with respect to an electrical connector for receiving cautery current from a power supply source. Levinson teaches of an electrical connector for attachment to a cauterizing endoscopic snare (see Col. 5, Lines 15-20). It would have been

Art Unit: 3739

obvious to one skilled in the art at the time the invention was made to include such an electrical connector in on the device of Konomura in order to provide the snare loop with an electrical current and therefore assist in surgical procedures, as taught by Levinson and is well-known in the art.

In regards to claim 33 and 46, Konomura discloses a medical device wherein the distal member defines a plurality of flow paths (see Fig. 5).

Claims 5-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,682,599 to Konomura in view of U.S. Patent No. 6,660,011 to Levinson in further view of U.S. Patent No. 5,599,324 to McAlister et al.

In regards to claims 5-7, Konomura and Levinson disclose a medical device but are silent with respect to a fluid supply member (syringe) for supplying fluid to the port, an interlocking member and fluid chamber sealed from a portion of the handle. McAlister et al. teach of an analogous device in which a physician can attach a syringe or other device to the second entry port 31 and force a contrast agent through the passage 35, the central volume 33 and the lumens 23 and 24 in parallel to be discharged where the lumens 23 and 24 exit the distal end 17. The seals formed between the tube 36 and the handle 12 and between the tube 36 and the catheter tube 11 around the guidewire 22 assure isolation of the guidewire lumen 22 (see Col. 5, Lines 13-22). It would have been obvious to one skilled in the art at the time of the invention to include a fluid supply assembly in the device of Konomura and Levinson so if it is necessary to relocate the distal tip 20, there is no need to remove the guidewire as taught by McAlister et al.

Claims 69-75, 81-82, 89, 93 and 101 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,682,599 to Konomura in view of U.S. Patent No. 6,660,011 to Levinson in further view of U.S. Patent No. 5,871,440 to Okada.

In regards to claims 69, 89 and 93, Konomura and Levinson discloses a medical device comprising: a proximal handle; an elongated member 2 having a proximal end, a distal end, and a lumen there between, the proximal end being coupled to the proximal handle, the elongated member being sufficiently flexible to traverse through tortuous anatomy of a patient's body; a tissue cutting end effector proximate the distal end of the elongated member, actuation of the proximal handle 14 causing the end effector to sever tissue; and a distal member configured to open and substantially close the distal end of the lumen, the distal member defining a flow path such that, when the distal member substantially closes the distal end of the lumen, the flow path enables a flow communication between the lumen and an outside of the elongated member. Konomura and Levinson are silent with respect to wherein at least a portion of the flow path has a cross-sectional flow area smaller than both a cross-sectional flow area of an inlet of the flow path and a cross-sectional flow area of an outlet of the flow path. Konomura teach that the number of openings is not limited and that a plurality of openings may be formed through which fluid may be passed (see Col. 4, Lines 36-65). Okada teaches of an analogous surgical instrument having a nozzle 374 for dispensing fluid. Okada teaches of a nozzle capable of having a large variety of configurations and cross-sectional flow paths to effect the outputted fluid and in particular a nozzle wherein at least a portion of the flow path there-through has a cross-sectional flow area smaller

Art Unit: 3739

than both a cross-sectional flow area of an inlet of the flow path and a cross-sectional flow area of an outlet of the flow path (see Fig. 30b). It would have been obvious to one skilled in the art at the time the invention was made to vary the cross-sectional flow area in the apparatus of Konomura and Levinson in order to have greater control over the outputted flow of fluid as taught by Okada and is well known in the art. **In regard to claims 70-75, 81-82 and 101** see the rejections stated above with respect to Konomura and Levinson.

Claims 87-88 and 102 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,682,599 to Konomura in view of U.S. Patent No. 6,660,011 to Levinson in further view of U.S. Patent No. 4,204,528 to Termanini.

In regards to claims 87, Konomura and Levinson discloses a medical device comprising: a proximal handle; an elongated member 2 having a proximal end, a distal end, and a lumen there between, the proximal end being coupled to the proximal handle, the elongated member being sufficiently flexible to traverse through tortuous anatomy of a patient's body; a tissue cutting end effector proximate the distal end of the elongated member, actuation of the proximal handle 14 causing the end effector to sever tissue; and a distal member configured to open and substantially close the distal end of the lumen, the distal member defining a flow path such that, when the distal member substantially closes the distal end of the lumen, the flow path enables a flow communication between the lumen and an outside of the elongated member.

Konomura and Levinson are silent with respect to wherein the flow path comprises an inlet and a plurality of outlets connecting to the inlet. Konomura teach that the number

Art Unit: 3739

of openings is not limited and that a plurality of openings may be formed through which fluid may be passed (see Col. 4, Lines 36-65). Termanini teaches of an analogous surgical instrument having head 36 with apertures 40 to permit injection of a solution into the body during operation (See Figs. 1-2 and 6-7). It would have been obvious to one skilled in the art at the time the invention was made to vary the outlet area in the apparatus of Konomura and Levinson in order to have greater control over the outputted flow of fluid as taught by Termanini and is well known in the art. **In regard to claims 88 and 102** see the rejection stated above with respect to Konomura and Levinson.

Response to Arguments

Applicant's arguments filed June 22, 2007 have been fully considered but they are not persuasive.

Applicant states the combination of Konomura and Levinson fails to disclose a snare loop or a tissue cutting end effector consisting of *essentially* a snare loop. Examiner disagrees. Levinson teaches of a set of wires 28 that is a snare loop and functions as the tissue cutting end effector. The device 10 includes a connector for connecting the second set of wires 28 to a source of power, for energizing the second set of wires so that the wires cut tissue captured within the second set of wires (see Fig. 5 and Col. 5, Lines 15-20). The first set of wires 20 are not part of the *tissue cutting* end effector of Levinson. The first set of wires 20 are used for capturing and retrieving the cut tissue and have no affect on the tissue cutting performed by wires 28. Thus, as broadly as claimed, the combination of Konomura and Levinson disclose a tissue cutting end effector that is a snare loop.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, It would have been obvious to one skilled in the art to combine the device of Konomura and Levinson with Okada or Termanini in order to have various outputs of fluid flow delivery, determined by the flow path of the nozzle. Both Okada and Termanini teach of endoscopic instruments used to deliver fluid therethrough to within the body during a surgical procedure via numerous flow path configurations. Okada teaches of an analogous surgical instrument having a nozzle 374 for dispensing fluid. Okada teaches of a nozzle capable of having a large variety of configurations and cross-sectional flow paths to effect the outputted fluid and in particular a nozzle wherein at least a portion of the flow path there-through has a cross-sectional flow area smaller than both a cross-sectional flow area of an inlet of the flow path and a cross-sectional flow area of an outlet of the flow path (see Fig. 30b). Termanini teaches of an analogous surgical instrument having head 36 with apertures 40 to permit injection of a solution into the body during operation (See Figs. 1-2 and 6-7). Varying the nozzle configuration in the device of Konomura and Levinson would aid in the removal of foreign matter from a target site within the body, as providing alternate nozzle configurations (such as those

Art Unit: 3739

taught by Okada and Termanini) would allow for greater accuracy and efficiency when delivering fluids, such as contrast agents, during an assortment of different surgical procedures.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

Art Unit: 3739

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew J. Kasztejna whose telephone number is (571) 272-6086. The examiner can normally be reached on Mon-Fri, 8:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C.M. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MJK *MJK*

8/27/07



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